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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,930

06/29/2006

Susan Ashwell

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EXAMINER

JEAN-LOUIS, SAMIRA JM

ART UNIT

PAPER NUMBER

1627

MAIL DATE

DELIVERY MODE

11/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,930	Applicant(s) ASHWELL ET AL.	
	Examiner SAMIRA JEAN-LOUIS	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-45 is/are pending in the application.
- 4a) Of the above claim(s) 38-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/23/08, 06/22/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 37-45 are currently pending in the application.

Applicant's election of Group I (i.e. the compound, 5-(3-Fluorophenyl)-3-ureidothiophene-2-carboxylic acid (S)-piperidin-3-ylamide) in the reply filed on 08/30/10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Thus, the requirement is deemed proper and is therefore made FINAL.

Claims 38-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups, there being no allowable generic or linking claim. Claim 37 is examined on the merits herein.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(e) for domestic priority based on applications 60/534,310 and 60/553,305 filed in the U.S., which papers have been placed of record in the file. However, the Examiner maintains that the compound of group I only find supports in the instant application which was filed June 29th, 2006. Consequently, the earliest priority date accorded to claim 37 for examination purposes is June 29th, 2006.

IDS

The information disclosure statements (IDS) submitted on 10/23/08 and 06/22/10 are acknowledged and have been entered. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

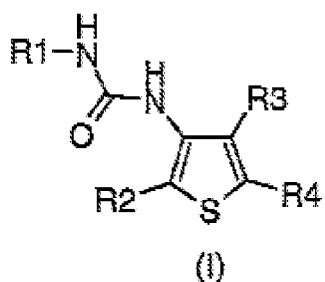
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 37 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Parrish et al. (WO 03/028731 A1, cited by applicant and filed on an IDS 1449).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Parrish et al. teach CHK1 kinase inhibitors that are novel compounds and that have been found useful in the inhibition of damage response kinases as well as various forms of cancer and hyperproliferative diseases (see abstract and pg. 1, top paragraph). Specifically, Parrish et al. teach compounds of formula (I):



wherein R1 is H; R2 is C(O)NHR5 with R5 being a C0alkyl heterocyclyl; R3 is H and R4 is an aryl optionally substituted by A wherein A is a halogen (see pg. 2, compound of formula (I) and pg. 3). By alkylheterocyclyl, Parrish et al. teach that the term means a heterocyclic group attached to an alkyl group and heterocyclyl means a saturated 5-10 membered ring system in which the ring contains one or more heteroatom such as nitrogen and which may be optionally substituted with hydrogen (see pg. 6, paragraph 2 and pg. 7, paragraph 3). Additionally, Parrish et al. teach that the aforementioned compounds can also be formulated as esters, prodrugs, or pharmaceutically acceptable

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inorganic or organic salts and complexes thereof including acid addition salts or basic addition salts (see pg. 5, paragraph 2 and pg. 9, paragraphs 4-6).

Parrish et al. do not specifically teach the compound, 5-(3-Fluorophenyl)-3-ureidothiophene-2-carboxylic acid (S)-piperidin-3-ylamide.

The Examiner however contends that the compound of formula (I) of Parrish does indeed render obvious the compound of claim 37 since such compound is encompassed by the generic formula (I) of Parrish and given that Parrish teaches that such compounds can be synthesized as novel CHK1 kinase inhibitors.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the compounds encompassed by formula (I) of Parrish including 5-(3-Fluorophenyl)-3-ureidothiophene-2-carboxylic acid (S)-piperidin-3-ylamide given that Parrish et al. teach synthesis of such compounds as CHK1 kinase inhibitors. Given the teachings of Parrish et al., one of ordinary skill would have been motivated to utilize the compound of formula (I) of Parrish including 5-(3-Fluorophenyl)-3-ureidothiophene-2-carboxylic acid (S)-piperidin-3-ylamide with the reasonable expectation that such compounds are effective in inhibiting CHK1 kinase and effective in treating hyperproliferative diseases.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

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10/25/2010

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627